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REMARKS

In the Final Office Action mailed on May 4, 2007, claims 1-29 and 73-90 were pending. Claims 5-8 were withdrawn from consideration, and claims 1-4, 9-24, 26-29, 73-80, and 82-85 stand rejected. Claims 86-90 have been allowed, and claims 25 and 81 have been objected to but indicated allowable if rewritten in independent form incorporating the base claim and any intervening claims. Reconsideration of the present application in view of the remarks that follow is respectfully requested.

Claims 1-4, 9, 10, 15-24, 26-29, 73-80 and 82-85 were rejected under 35 USC §103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0020254 to Cook et al. (hereafter "Cook") in view of U.S. Patent Application Publication No. 2006/0074425 to Sutterlin et al. (hereafter "Sutterlin.") With respect to claim 1, the Final Office Action asserts that Cook discloses "a guide instrument including a guide member (page 3, paragraph 1)." The Final Office Action further admits that Cook fails to disclose the specifics of the guide member, but asserts that it would have been obvious to one skilled in the art at the time the invention was made to have used the guide instrument of Sutterlin with the device of Cook "because it overcome the drawbacks of the prior art provided by the methods disclosed in paragraph [0023]" of, presumably, Sutterlin.

It is respectfully submitted that even if the references were combinable, the combination fails to teach or suggest all the elements of claim 1. Specifically, Sutterlin is concerned with providing an instrument for rapid tissue removal in surgical procedures in a spinal disc space and other locations. Sutterlin discusses the drawbacks in the prior art at, for example, paragraphs [0007], [0008], [0011], which are identified as being associated with soft tissue removal by mechanical devices and energy focusing techniques. A specific problem is identified with removal of intervertebral disc material in that only small portions of tissue are removed by existing tools, resulting in time-consuming removal procedures. However, Sutterlin does not identify any drawbacks or problems associated with tissue removal to form a recess between a hole formed in tissue and a defect in an annulus. Nor does it identify any drawbacks or problems associated with guiding an instrument for forming a hole in tissue and guiding a cutting instrument for forming a recess in the tissue. Furthermore, as discussed below and in contrast to

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the guide instrument recited in claim 1, the instrument in Sutterlin is not adapted to address these drawbacks.

Sutterlin teaches that the need to provide a device for rapidly removing body tissue is addressed by an instrument that comprises a brush member 12 for introduction into a body. With respect to spinal procedures, Sutterlin teaches brush member 12 may "be dimensioned to be introduced into an intervertebral space to receive, carry, and remove intervertebral disc material. In particular, the brush member may be used to remove intervertebral disc material in order to thereafter introduce a spinal implant into the intervertebral space. In another related aspect, the brush member may be dimensioned to be introduced into a vertebral body to receive, carry, and remove osseous material." See paragraph [0017]. Sutterlin further teaches that the instrument includes a protector that is a cannula 16 with an inner dimension to slidably receive brush member 12. See paragraph [0044]. Cannula 16 has a distal end with lip 22, and the distal end completely encircles brush member 12. Cannula 16 thus establishes a barrier between brush member 12 and any body tissue around cannula 16. See paragraphs [0018], [0019] and [0044]. Since brush member 12 has an outer dimension that is smaller than the inner dimension of cannula 16, it must extend distally from cannula 16 to be used to remove tissue. As such, the distal end of cannula 16 cannot be positioned where brush member 12 is positioned while brush member 12 removes tissue.

For these reasons, Sutterlin fails to teach or suggest any guide instrument with a distal portion and a guide member that is "adapted to guide an instrument for forming a hole in the tissue to receive the at least one anchor, said guide member being further adapted to guide a cutting instrument for forming a recess in the tissue extending between the hole and the defect while said distal portion is positioned in the defect." Claim 1 sets forth structural attributes of interrelated components of the guide instrument, i.e. the distal portion and the guide member, that are not taught or suggested by the cited references, either alone or in combination. The instrument 10 in Sutterlin is not adapted to nor is it capable of guiding brush member 12 for forming a hole in the tissue and also guide brush member 12 for forming a recess between the hole in the tissue and a defect while the distal end of cannula 16 is positioned in the defect.

There is no prohibition to defining claimed structure in the terms of function. See, the Manual of Patent Examining Procedure (MPEP) §2173.05(g) (citations including, Innova/Pure

Water, Inc. v. Safari Water Filtration Sys. Inc., 381 F.3d 1111, 1117-20, 72 U.S. P.Q.2d 1001, 1006-08 (Fed. Cir. 2004) (interpreting functional language in apparatus claims and giving patentable weight thereto)). It is further noted that MPEP §2173.05(g) states “[a] functional limitation must be evaluated and considered, just like any other limitation in the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.” The MPEP goes on to further to refer to In re Venezia, 189 USPQ 149 (C.C.P.A. 1974) and recites “[i]n a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as ‘members adapted to be positioned’ and ‘portions ... being resiliently dilatable whereby said housing may be slidably positioned’ serve to precisely define structural attributes of interrelated component parts of the claimed assembly.” In addition, the CCPA in In re Land, 151 USPQ 621, 635-636 (C.C.P.A. 1966) states “[i]t is true that the italicized portions [of claim 70] are ‘functional’ but we do not regard that as good ground to give them ‘no weight’ in view of the third paragraph [currently sixth paragraph] of 35 U.S.C. 112. We give them weight and with the limitation we think claims 70 and 71 are limited to deferred diffusion *built into the structure recited*, thereby being limited to the actual invention disclosed and hence allowable for the same reasons given by the board....” (Emphasis in original).

Furthermore, the case of In re Mills, 16 USPQ2d 1430 (Fed. Cir. 1990) involved functional limitations that were assigned patentable weight by the Federal Circuit. In this case, the claims were rejected as obvious because the difference between the claim and the cited references lay “solely” in the functional language of the claims. Id. at 1432. The Federal Circuit reversed on appeal, acknowledging that the difference between the claim and the prior art lay specifically in the functional limitations. Nevertheless, the Federal Circuit held the claim nonobvious over the prior art based on the functional limitations. Id. at 1433. Accordingly, functional language in a claim cannot be ignored for the purposes of patentability, and a prior art reference or combination of references must disclose or suggest the functional limitations of a claim, in addition to the structural limitations, to support a determination of unpatentability.

Claims depending from claim 1 that were rejected under 35 USC §103(a) as being unpatentable over Cook in view of Sutterlin are also allowable. For example, claim 20 recites “wherein said guide instrument member further comprises a positioning flange extending distally

from said guide member and offset from said passage.” There is no structure corresponding to the positioning flange extending distally from cannula 16 since lip 22 extends radially outwardly from cannula 16. Claim 21 depends from claim 20 and recites “wherein said positioning flange comprises a portion of a positioning member, said positioning member including a body mounted to said guide member, said positioning flange extending distally from said body.” The Final Office Action fails to identify where Sutterlin teaches or suggests any positioning member with a body mounted to cannula 16 and a flange extending distally from such a body. A review of the Final Office Action does not find any indication that either reference discloses or teaches a positioning member as recited in claim 21. Therefore, a prima facie case for rejecting claim 21 has not been properly established. Claim 22 recites “wherein said body includes a slot therethrough aligned with and in communication with said slot of said guide member.” Sutterlin also fails to disclose or suggest any slot extending through a body of a positioning member mounted to the guide member. Claim 28 recites “wherein said cutting instrument includes an elongated shaft positionable in said passage, said cutting instrument further comprising a blade extending from said shaft through said slot and movable along said slot with movement of said shaft along said passage.” The Final Office Action fails to identify any structure that corresponds to the cutting blade extending through the slot. Rather, as discussed above, Sutterlin teaches away from cutting instruments such as a blade by providing a brush member 12 for rapid tissue removal. Accordingly, withdrawal of this basis of the rejection of claims 2-4, 9, 10, 15-24, and 26-29 depending from claim 1 is respectfully requested.

Claim 73 is allowable for the reasons provided above and for other reasons. For example, claim 73 specifically recites “said guide member further including a slot extending through said distal end thereof in communication with said passage, said slot for receiving and guiding a cutting instrument for forming a recess in the tissue between the hole and the defect.” (Emphasis added.) The Final Office Action identifies element 20 in Sutterlin as teaching a slot. However, element 20 does not extend through a distal end of cannula 16 or through the distal end of any other structure. As shown in Figure 1, cannula 16 includes a radially extending lip 22 at its distal end, and the distal end completely encircles the passage of cannula 16. Element 20 terminates at a location that is substantially proximally located of lip 22 and the distal end of cannula 16. The Final Office Action fails to provide any indication of how it is considered that

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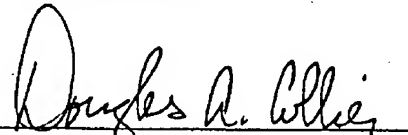
either Cook or Sutterlin teaches or suggest a slot extending through a distal end of a guide member as recited in claim 73. Therefore, a prima facie case for rejecting claim 73 has not been established and withdrawal of the rejection of claim 73 is respectfully requested. Claims 74-80 and 82-85 depend directly or indirectly from claim 73 and are also allowable for the reasons provided above.

Claims 11-14 were rejected under 35 USC §103(a) as being unpatentable over Cook et al. alone. The Final Office Action recognizes that Cook alone fails to disclose or suggest all the elements of claim 1. Therefore, Cook alone cannot disclose or suggest all the elements of claims 11-14, which depend directly or indirectly from claim 1. Therefore, a prima facie case for rejecting claims 11-14 has not been properly established, and withdrawal of this basis of the rejection of claims 11-14 is respectfully requested.

In view of the foregoing amendments and remarks, claims 1-29 and 73-90 are in condition for allowance, and a Notice of Allowance is hereby solicited. The undersigned would welcome an interview with the Examiner to resolve any outstanding issues with regard to the present application

Respectfully submitted,

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